



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,604	12/07/2001	Pablo D. Garcia	002441.00008	6543

7590 11/15/2004
Chiron Corporation
Intellectual Property
P.O. Box 8097
Emeryville, CA 94608-2916

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,604

Applicant(s)

GARCIA ET AL.

Examiner

Ulrike Winkler

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-11 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1648

DETAILED ACTION

The Amendment filed August 4, 2004 in response to the Office Action of March 10, 2004 is acknowledged and has been entered. Claims 8, 12 and 16-38 have been cancelled. Claims 1-7, 9-11, 13-15 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Objections

The objection of claims 8, 9, 10, 12, 13, 14 and 15 as being in improper form because a multiple dependent **is withdrawn** in view of Applicant's amendments to the claims and cancellation of claims 8 and 12.

Claim Rejections - 35 USC § 112

The rejection of claims 1-3, 8-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** for reasons of record. In an attempt to clarify what is included with the term HML-2 applicants have amended the claims to read "human endogenous MMTV-like subgroup 2 (HML-2)." The new claim language does not help identify the structure required for the purpose of diagnosis.

The rejection of claims 1-3, 9-11 and 13-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is maintained** for reasons of record.

Art Unit: 1648

Applicant's arguments have been fully considered but fail to persuade. Applicant's amendment does not help to identify the particular virus contemplated for the detection of prostate cancer. The specification on page 37, lines 13-15 reads "Preferred members of the HML-2 family for use in accordance with the present invention are those whose proviral genome has an LTR which has at least 75% sequence identity to SEQ ID NO: 150." The claims are drawn to method of diagnosing prostate cancer by detecting the presence of HML-2 or by having at least 75% sequence identity to the polynucleotide of SEQ ID NO: 150. The claims do not require that the polynucleotide possesses any particular distinguishing feature or conserved structure. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The art indicates that HML-2 comprises a group of retroelements (Zsiros et al. Journal of General Virology, 1998, listed on IDS; see figures) having diverse structures at the nucleic acid level. A definition by function alone "does not suffice, to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the isolated polynucleotide sequences that have actually been correlated with prostate cancer meet the written description provision of 35 U.S.C. §112, first paragraph.

Art Unit: 1648

The rejection of claims 1-7, 9-11 and 13-15 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained** for reasons of record. Applicant's amendment does not help to identify the particular virus contemplated for the detection of prostate cancer. The specification on page 37, lines 13-15 reads "Preferred members of the HML-2 family for use in accordance with the present invention are those whose proviral genome has an LTR which has at least 75% sequence identity to SEQ ID NO: 150. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the myriad of nucleic acids and oligonucleotides. The art indicates that HML-2 comprises a group of retroelements (Zsiros et al. Journal of General Virology, 1998, listed on IDS; see figures) having diverse structures at the nucleic acid level. Applicants have not provided sufficient teaching to show that all HML-2 variants are predictably associated with prostate cancer. Applicants have argued that "diagnosis" according to the invention can range from definite clinical diagnosis of disease to an indication that the patient should undergo further testing which may lead to a definite diagnosis"

Applicants have not provided sufficient showing that an increase in the HML-2 level in the blood correlates with only prostate cancer. HML-2 can be found in other tissues [Medstrand et al. Journal of Virology, 1993, listed on IDS] such as placenta and kidney, therefore, and increase in the level of HML-2 in the blood will not be indicative of prostate cancer as the increase could be due to pathologies found in the kidney or placenta. HML-2 is also detected in the PBMCs of healthy donors [see Andersson et al. Aids Research and Human Retroviruses, 1996, see figures 2 and 6]. Therefore, it would not be predicable whether the presence of HML-2 in blood would be

Art Unit: 1648

indicative of prostate cancer because HML-2 is normally found in blood. The MMTV-like viruses have been associated with human breast cancer [see Yin et al. AIDS Research and Hum Retroviruses, 1997, see abstract]. Men are also susceptible to developing breast cancer, although rarely [see Perkins et al. BMJ, 2003]. Therefore, detection of HMML-2 in male tissue such as blood could not provide information regarding the status of the prostate in the patient. The rejection is maintained.

Claim Rejections - 35 USC § 102

The rejection of claims 1-3 and 11 under 35 U.S.C. 102(a) as being anticipated by Wang-Johanning et al. [American Association for Cancer Research Annual Meeting (March 1999) Vol. 40, page 424, Abstract # 2801] **is withdrawn** in view of applicants argument.

Claim Rejections - 35 USC § 103

The rejection of claims 1-7 and 11 under 35 U.S.C. 103(a) as being unpatentable over Wang-Johanning et al. [American Association for Cancer Research Annual Meeting (March 1999) Vol. 40, page 424, Abstract # 2801] and Barbulescu et al. [Current Biology (August 1999)] **is withdrawn** in view of applicant's arguments.

New Objection:

Claim 11 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

Art Unit: 1648

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

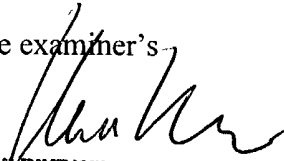
Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.


ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER